

Peer Review

Review of: "How Well Are We Protecting Human Research Subjects?"

Hany Akeel Al-hussaniy¹

1. University of Baghdad, Iraq

This commentary provides a thoughtful and historically grounded discussion of the evolution of human research subject protections, effectively tracing the transition from the Institutional Review Board (IRB) framework to comprehensive Human Research Protection Programs (HRPPs). The article's major strength lies in its clear narrative linking regulatory milestones—including the Belmont Report, the Common Rule revisions, and accreditation frameworks—to contemporary ethical oversight challenges. Additionally, the emphasis on the need for measurable performance metrics for evaluating research participant protection represents a valuable and timely conceptual contribution. However, the manuscript would benefit from further critical examination of the proposed performance metrics. Specifically, while the five metrics focusing on adverse events, informed consent violations, privacy breaches, and IRB oversight failures are logically justified, the discussion does not sufficiently address their potential limitations, such as variability in reporting standards across institutions, underreporting of non-serious ethical harms, and differences in regulatory environments internationally. Furthermore, the commentary would be strengthened by incorporating empirical examples demonstrating how these metrics could be implemented in diverse research settings, including low- and middle-income countries where ethical governance structures may differ substantially. Expanding the discussion to include emerging ethical challenges such as digital health research, artificial intelligence-driven clinical trials, and decentralized trial models would also improve the article's future relevance. Overall, this commentary provides an important conceptual framework for evaluating human subject protections, but additional critical analysis and broader contextual integration would enhance its scholarly and practical impact.

Declarations

Potential competing interests: No potential competing interests to declare.